caBIG Workspace Developer Project Form

Developers, please complete this form in advance of the caBIG kickoff meeting and return by e-mail to adamsm@mail.nih.gov. Completed forms will be made available to all participants in advance of the meeting to enhance workspace discussions. During our conversations with you, we expressed the aspect of your program that we would like you to develop in the first year of the caBIG pilot; it is this we are asking you to address - here and in your presentation.

Sponsoring Cancer Center
University if Pittsburgh Cancer Institute
Center for Pathology and Oncology Informatics

2. Workspace
Clinical Trials Workspace

3. Projects or Activities
UPCI Clinical Trials Management Applications and Modules

4. Workspace needs the project meets

We divide the clinical trials lifecycle into 4 critical areas:

- Research development and pre-trial setup
- Patient enrollment and management
- CT administrative and reporting
- Data mining and analysis

The UPCI Clinical Trials Management Applications (CTMA) provides functionality in all four of these areas to support aspects of all four lifecycle areas.

5. Stage of project maturity
The system has been operational at UPCI since March 2000 and is founded on a previous clinical trial management database developed in 1994. We have an ongoing development and evaluation effort to improve the application and it currently supports more than 200 clinical trials and contains data from approximately 16,000 patients.

6. Technical details of Tools

a. Software Architecture

i. System design

CTMA is a multi-tiered Java application. The first tier, the client, is an applet constructed from reusable UI framework Swing components, and is accessible via any standard web browser with the Java Plug-in installed. It uses RMI to communicate, via SSLava, to the middle tier. Client authentication security is conducted by iPlanet's LDAP server and also via Oracle.

The middle tier, the data access server (DAS), is a Java application. The DAS handles all remote calls, using RMI to exposes various generic routines/objects to the client, to managed calls to the database. This runs on a Windows NT machine designated as intranet host (could be any host machine). The DAS uses the Oracle Type 4 Thin SQL driver, with Oracles RC4_56 encryption algorithms to support the JDBC communication between DAS and the Oracle server.

The third tier an Oracle 9i database which resides on a SUN Solaris Unix server.

ii. Component details

CTMA provides functionality in the following component sets:

- Administrative and Regulatory Management
- Clinical Research Management
- Study Parameters
- Financial Management

Administrative and Regulatory Management Component

Administrative Summary

Provides the ability to collection and view information on status, study scope, population accruals, regulatory submission requirements and investigator financial interesting (of which were derived from the PRC Checklist).

Multi-Classifications

This allows the specification of multi-classification categories such as multiple disease sites and centers. Also, designations of multi-performance sites and resources can be specified.

Trial Participants

The administrative offices can track and designate contact information for the various researchers and organizations, which are participants on the trial. These include primary investigator, co-investigators, coordinators, bio-statisticians, data manager and sponsoring organizations, CROs, etc.

Event/Activity Calendar

With CTMA, all event-related activities from approval dates to capturing staff work tasks can be captured and used for reporting and workload analysis.

Integrated Email

Integrated within the Event Calendar, the email feature uses SMTP to facilitate communication of IRB approval status to investigators and correspondences tracking to internal and external participants from a central location.

Electronic Document Integration

Provides access to all associated documents (i.e., consents, summaries) for quick viewing or editing. Includes support for MS Word and Adobe PDF, document types.

Web Content Support

Supports real-time content updates for online clinical trials information on the UPMC Cancer Center public Internet site

Using designated pre-defined "case report forms"; a variety of patient-related clinical data can be captured. (i.e., Adverse Events Physician Notes, etc)

Clinical Research Management Components

Patient Enrollment Registry

Allows the user to register and track enrollment of patients onto the clinical trials. This screen collects treatment and referring physician, vitals, and BSA calculations at the time of registration. Also, overall patient accruals are monitored for enrollment compliancy.

Patient Calendar/Treatment Progress Chart

Provides a "day-planner" view of all patient activities such as treatment start date. Allows treatment calendars to be generated and printed from the study Treatment Schedule. Integrated with billing component to allow automated triggering of billable events

Study Parameters Components

User-defined Parameters

A user can define various study parameters with CTMA, such as dosage tiers, drug agents and treatment arms.

CRF Collection Schedule

This allows a case report form collection schedule to be pre-defined for each study. Combined with reporting, this will identify what and when each CRF will/has be/been collected for each patient on study.

Treatment Schedule

Allows a study treatment schedule to be pre-defined by the researcher or coordinator, in a matrix-like format, utilizing treatment events, cycles and occurrence period. This schedule is then applied to the patient's treatment calendar based on the start of treatment date. This allows treatment progress charts to be viewed in real-time.

Financial Management Components

Treatment Schedule/Cost-mapping

Utilizing the study Treatment Schedule pre-defined by the researcher or coordinator, this will allow financial data to be linked to the treatment events, in a matrix-like format, utilizing a cost-mapping feature.

Institutional Accounts

Allows the designate of institutional specific account numbers for linkage to ancillary billing systems.

iii. Relevant standards

In general and where possible, we have standardized with our Cancer Registry System which uses various industry standard vocabularies and also with UPMC standards.

Component Concept	**Vocabulary/Standard**
• Adverse Events (AE's)	NCI CTCAE (2.0 & 3.0) (Common Toxicity Criteria Adverse Events)
• Organizations	CTEP/CDUS Institution (Cancer Therapy Evaluation Program /Clinical Data Update System)
Study Subject parameters	
Disease Site	ICDO3
Disease Histology	ICDO3
CTEP Disease Code	MedDRA—for CTEP/CDUS reporting only (Medical Dictionary for Regulatory Activities)
Staging	AJCC (American Joint Committee on Cancer)
Performance Status	ECOG/Zubrod & Karnofsky
Race/Ethnicity	SEER
Study/Trial parameters	
Disease Site Treated	SEER
Interoperability	
Appointment Schedules	UPMC HL7 records transmitted to UPMC message router
Reporting	Crystal Reports
	(Produces output in various electronic formats including XML)
External Data Acquisition	
External System	**Method and Usage**
Impac Cancer Registry	Oracles Heterogeneous Services To display/validate historical diagnosis, treatments, f/u, etc. Statistical reports (grant funding, trial feasibility)
CoPath	Oracles Transparent Gateway for Sybase Not in use at this time, future plans are to display path results within clinical trials Possible SPIN parsing for diagnosis, other codings
Ingres	JAVA/jdbc Not is use at this time, previously used to send/receive data while in the initial re-engineering phase of clinical trials
UPMC Enterprise Master Patient Index	Oracle database link Used to validate and capture study subject demographics
NCI CTEP/CDUS	ftp transmit

	For CDUS reporting requirements on clinical trials
UPCI Scheduling	UPMC message router (transmit HL7 Scheduling) Transmit HL7 scheduling records Radiology/Stentor retrieves these records for pre-fetching of radiology images and reports
Social Security Death Index	Quarterly load of ceased to breathe data from CD Updates patient master with ctb data
Misys/Sunquest Lab Results	UPMC message router Currently working on retrieving HL7 lab records

In previous years, we have attempted to incorporate and standardize on SNOMED-RT (Systematized Nomenclature of Medicine) and then on UMLS (Unified Medical Language System). At that time, these products were not yet ready for production use therefore we postponed the initiative.

Most of the vocabulary and nomenclature standards are constructed as external tables or resources that can be loaded at run time. These are standards currently in use, but the architecture has been designed to be flexible to accommodate the evolving vocabulary standards.

iv. UML schematics (if valid)

See diagram included at the end of description

v. Size of project installed software base

We currently support 100+ users of the system, at various levels.

b. Development Environment (tools, languages, bug tracking, etc.)

IDE: JBuilder 8
Languages: Java, Perl, Coldfusion
Tools: JClass, SSLava
CM: CVS
Bug tracking: Homegrown (Coldfusion/Oracle)

7. Does the project make use of existing standards? If so, what are they? (e.g. bioinformatics standards such as MIAME for microarrays, or software standards such as XML)

See complete listing above

8. Does other software in the community meet this need? Is this software open source? Can it be harnessed?

CTMA integrates into some proprietary software applications, most notably oracle databases, and the report generation functions. We have build some interfaces into other systems, particularly the clinical systems at UPCI, but have tried to use

HL7 and other standards whenever possible . Our intention is that CTMA will be made available as an open-source resource as the project continues.

9. Points of possible interoperability with other caBIG systems
(This might include communication with other caBIG databases, use of caCORE APIs, caBIG-compatible APIs, etc.)

In the first year, we envision two points of interoperability with caCORE APIs. First, terms within CTMA could be drawn from existing caBIO EVS APIs to access standardized vocabularies directly from within search dialog boxes. Coordination with the vocabulary and architecture groups would be needed to accomplish this task.

Second, we would begin the migration toward caBIG CDE standards, moving our database and java code standards closer to the caBIG standards.

10. What resources are proposed to achieve caBIG interoperability?
    a. Developmental requirements
        i. Software (re)engineering
        ii. Standards adoption
        iii. Platform migration
    b. Infrastructure
        i. Facilities
        ii. Management tools
        iii. Personnel

11. Draft 12-month work plan, with milestones to achieve caBIG interoperability.

We propose a dual approach to achieving both caBIG interoperability and the dissemination of caBIG components.

User-centered design and evaluation
A principal barrier to successful adoption of standards-based application is not understanding the needs, context, and work processes that the technology is meant to support. We believe it is possible within the first 12 months to
1. Evaluate the work processes, information needs, and user requirements at an adopter site, in parallel with the evaluation process that is ongoing at UPCI. The result will be a contextual inquiry model of the users and organizations that will be implementing the UPCI CTMA applications, and a deep understanding of the information technology needs of clinical trials and their management. The two contextual inquiry models of UPCI and the adopter site will serve to aid in the generalizability of the application, and prioritize enhancements and development.
2. Implement CTMA in the adopter site(s) as it currently exists, educate the users in its use, and in month 12, evaluate the predictive capability of the contextual inquiry models to anticipate problems with implementation. At least one adopter site will be using CTMA for their ongoing clinical trials enrollment, with others also implementing CTMA as work load permits.

Additional sites and additional user-centered design and evaluation will be possible, contingent on resource availability.

Standards-centered development
In the first 12 months, we believe we can
1. Modify the existing CTMA terminology to access the caBIO EVS APIs and dynamically load caBIG compliant vocabulary structures into existing CTMA windows.
2. Develop tools and methods to incorporate the caCORE CDE APIs into the existing code in CTMA

3. Improve the modularization of the CTMA application and the communication between CTMA modules. Successful implementation of a subset of the current CTMA modules (for example, only the Adverse Event reporting, or Financial modules) will indicate successful modularization.

We recognize that much of the development work will be driven by adopter sites and by the needs for integration and standards development from the NCI. Additional work is possible as resources and priorities permit.

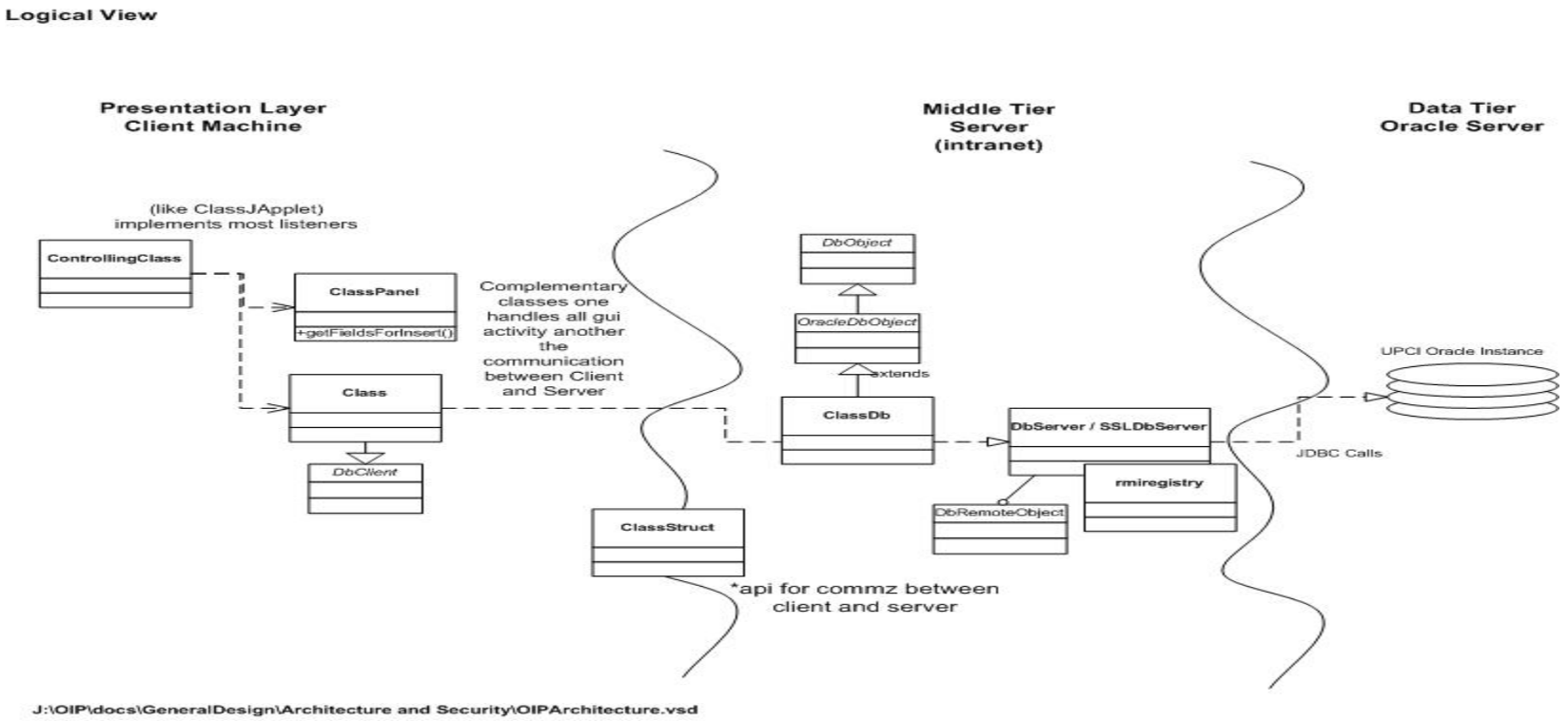

Figure 1 Three-tiered architecture of CTMA. A general description of the CTMA application and architecture.

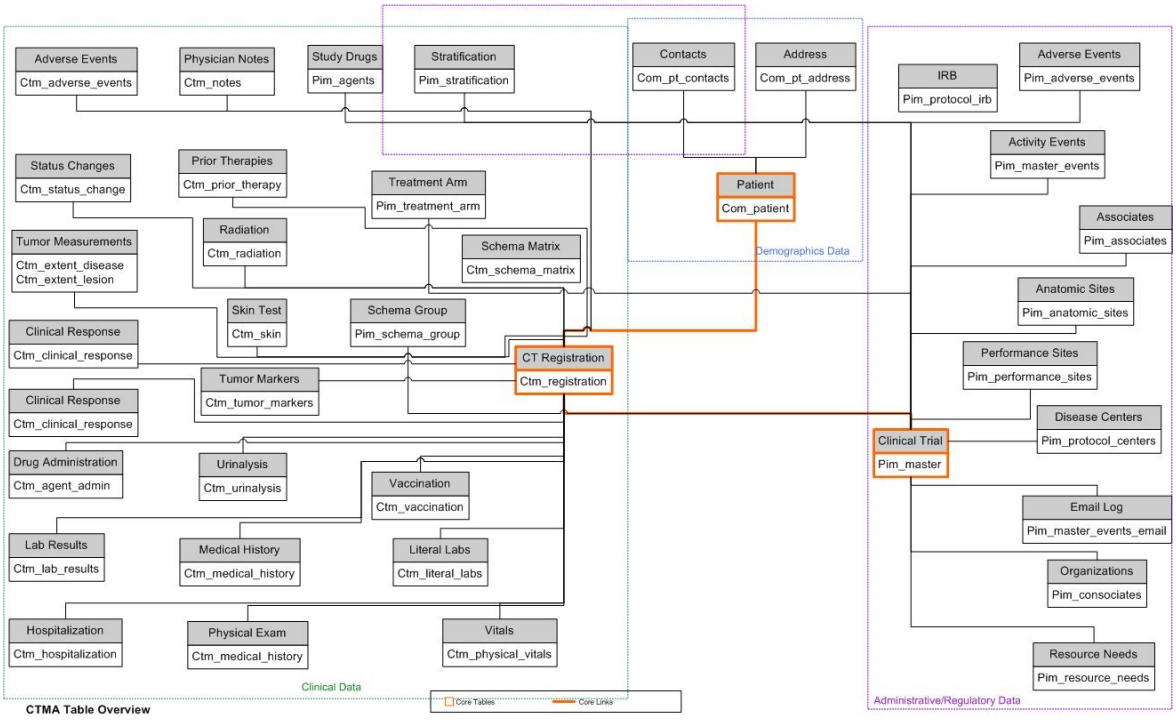

Figure 2 Data object overview This diagram shows the data object model in CTMA. The key links are between patient, CT registration and Clinical Trial.